control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

[55 FR 22790, Jun. 4, 1990; 55 FR 31186, Aug. 1, 1990]

§ 410.64 Services related to cardiac pacemakers and pacemaker leads.

(a) *Requirement.* (1) Physicians or providers that request or receive payment for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads, must submit to HCFA the information required for the pacemaker registry.

(2) The required information is set forth under 21 CFR part 805 of the FDA regulations and must be submitted in accordance with general instructions issued by HCFA.

(b) *Denial of payment.* If HCFA finds that a physician or provider has failed to comply with paragraph (a) of this section, HCFA will deny payment for the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead, effective 45 days after sending the physician or provider written notice in accordance with paragraph (c) of this section.

(c) *Notice of denial of payment.* The notice of denial of payment—

(1) States the reasons for the determination;

(2) Grants the physician or provider 45 days from the date of the notice to submit the information or evidence showing that the determination is in error; and

(3) Informs the physician or provider of its right to hearing.

(d) *Right to hearing.* If the denial of payment goes into effect at the expiration of the 45-day period, it constitutes an ''initial determination'' subject to administrative and judicial review under part 498 of this chapter.

[56 FR 8841, Mar. 1, 1991]

§ 410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in Mexico or Canada.

Conditions for payment of emergency outpatient services furnished by a nonparticipating U.S. hospital and for services furnished in Mexico or Canada are set forth in subparts G and H of part 424 of this chapter.

[53 FR 6634, Mar. 1, 1988; 53 FR 12945, Apr. 20, 1988]

§ 410.68 Antigens: Scope and conditions.

Medicare Part B pays for—

(a) Antigens that are furnished as services incident to a physician's professional services; or

(b) A supply of antigen sufficient for not more than 12 weeks that is—

(1) Prepared for a patient by a doctor of medicine or osteopathy who has examined the patient and developed a plan of treatment including dosage levels; and

(2) Administered—

(i) In accord with the plan of treatment developed by the doctor of medicine or osteopathy who prepared the antigen; and

(ii) By a doctor of medicine or osteopathy or by a properly instructed person under the supervision of a doctor of medicine or osteopathy.

[54 FR 4026, Jan. 27, 1989]

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

(a) *Basic rule.* Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist's assistant who is legally authorized to perform the services by the State in which the services are furnished.

(b) *Definitions.* For purposes of this part—

Anesthesiologist's assistant means a person who—

(1) Works under the direction of an anesthesiologist;